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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/743,080

12/23/2003

Atsushi Tomokuni

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08/10/2009

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1611

NOTIFICATION DATE

DELIVERY MODE

08/10/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/743,080	Applicant(s) TOMOKUNI, ATSUSHI	
	Examiner Lakshmi S. Channavajjala	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9 and 11-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-7, 9 and 11-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7-16-08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of declaration and response dated 05-12-09 is acknowledged.

Claims 1-7, 9 and 11-19 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5-12-09 has been entered.

In response to the amendment, the following rejections replace the rejections of record:

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7, 9 and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,346,507 to Watanabe et al (Watanabe) in view of EP 103910 (EP submitted on PTO-1449 on 7-16-08) and US 6,333,362 to Lorant OR over Watanabe et al in view of US 6,333,362 to Lorant.

Instant claim 1 is directed to a skin cleansing composition comprising:

Art Unit: 1611

- (A) 3 to 80 wt. % of an oil component,
 - (B) 1 to 45 wt. % of a hydrophilic nonionic surfactant,
 - (C) 1 to 45 wt. % of a lipophilic amphiphile which is at least one amphiphile selected from the group consisting of fatty alcohols having 8 to 25 carbon atoms, fatty acids having 8 to 25 carbon atoms and monoalkylphosphoric acids having 8 to 25 carbon atoms,
 - (D) 3 to 80 wt. % of a water soluble solvent and
 - (E) 3 to 80 wt. % of water,
- and having an isotropic liquid phase exhibiting a bicontinuous structure wherein, the weight ratio of the water soluble solvent (D) to the sum of the hydrophilic nonionic surfactant (B) and lipophilic amphiphile (C), $(D)/((B)+(C))$, is 1 or greater.

Watanabe teaches a liquid crystal composition in the form of a bi-continuous type microemulsion (col. 6, L 63-67) in makeup removing (cleansing) compositions for skin and hair. Watanabe teach liquid crystal microemulsions comprising 10-60% of a nonionic surfactant, 1-50% of a water-soluble substance with a hydroxyl group, 1-70% of silicone oil, up to 10-60% water (col. 2), which meet the instant components B, D, A and E respectively of claim 1. The specific surfactants, oils, solvents with OH groups are all described in col. 3, L 10 through col. 4, L 5 of Watanabe.

The specific nonionic surfactants of Watanabe in col. 3, L 11-28, include those recited in instant claims 5 and 6 (ex: polyethylene glycol fatty acid ester). The water soluble solvents of Watanabe (col. 3, L 29-54) read on those of instant claim 9.

Art Unit: 1611

For the claimed oils, Watanabe teaches hydrocarbon oils such as isoparaffin of claims 3 and 4 and hence the viscosity of claim 2 is implicit. Watanabe also teaches other oils (col. 4, L 35-50).

The amounts or percentages of components A, B, D and E in claims 1, 11, 13, 15 and 16 overlap with those taught by Watanabe.

While Watanabe does not teach the exact HLB of the hydrophilic surfactants of claim 1, 5 and 12, Watanabe teaches the surfactants for forming a surfactant phase, as also required in the instant application. Besides the surfactants described as nonionic by Watanabe includes the same surfactants described and claimed. Accordingly, burden is shifted to applicants to show that the surfactants do not meet the claimed HLB values. Instant claim 17 does not recite any specific substrate, whereas Watanabe recognizes cleansing or makeup removing compositions impregnated on tissue paper (background section of Watanabe).

The composition of Watanabe has a one phase system, either a liquid crystal phase and/or an isotropic surfactant continuous phase (col. 2, L 57-65). Watanabe states that that the mixture of nonionic surfactant, water soluble substance having a hydroxyl group, silicone oil in water form a homogenous reversed micelle isotropic solution, which is considered to be a bi-continuous type microemulsion. Watanabe further identifies nonionic surfactants to be amphipathic in nature for emulsifying the ingredients homogeneously. However, Watanabe fail to teach instant component C i.e., a lipophilic amphiphile that is at least one amphiphile selected from the group consisting

Art Unit: 1611

of fatty alcohols having 8 to 25 carbon atoms, fatty acids having 8 to 25 carbon atoms and monoalkylphosphoric acids having 8 to 25 carbon atoms.

EP teaches topical skin care composition in the form of a stable isotropic emulsion comprising 9% to 89% petrolatum, 10% to 90% water, 5% to 25% glycerin, up to 10% emulsifiers etc (abstract) for delivering active agents and emollients (pages 7-8). EP teaches emollients and skin conditioning agents such as fatty acids, fatty alcohols (page 8, Last paragraph and further Example A and B on page 26) and reads on the instant amphiphilic surfactants of the instant claims.

Lorant teaches a device comprising microemulsion for cleansing and care of the skin. The composition of Lorant comprises oil, at least one nonionic emulsifier, at least one foaming surfactant and water (col. 3, L 1-10 & L 42-49). For the oils, Lorant teaches the claimed silicone oils as well as fatty acids and fatty alcohols (col. 5, L 10-45). The nonionic emulsifiers of Lorant (col. 5, L 46-col. 6, L 25) read on the instant claimed one. The foaming surfactants according to Lorant may include any on the anionic, nonionic, cationic or amphoteric surfactants (col. 6, L 26-67). Lorant additionally teaches inclusion of coemulsifiers in the composition in an amount of 0.5 to 30% and includes the instant fatty alcohols of C12-C22, which is within the claimed 8 to 25 carbon atoms.

Thus, While EP does not teach fatty alcohol such as cetyl alcohol as coemulsifiers, the teachings of Lorant provide evidence that the fatty alcohol also acts as a coemulsifiers. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to the emollients such as the fatty

Art Unit: 1611

alcohols or fatty acids of EP OR include fatty alcohols of Lorant, in the compositions of Watanabe because EP suggests the claimed fatty acids and fatty alcohols as emollients and conditioner for treating dry skin and providing a barrier protection and Lorant suggests the use of C12-22 fatty alcohols as coemulsifiers as well as oils. Further, Lorant also suggests fatty alcohols such as oleyl alcohols, stearyl alcohol etc., as an essential oil component in preparing a microemulsion. Further EP states that the delivery of emollients and conditioners is optimum with the isotropic emulsion containing the components such as petrolatum, water, glycerin, emulsifiers. Therefore, one of an ordinary skill in the art would have expected not only cleansing and conditioning of the skin with the fatty acids or fatty alcohols of EP in the cleansing compositions of Watanabe but also for preparing microemulsions of suitable micron sizes because Lorant suggests fatty alcohols as both oily components and also coemulsifiers.

With respect to claimed ratio of the component D to the sum of components B and C being 1 or greater, all of the references are drawn to preparing emulsions in cleansing compositions and therefore optimizing the individual amounts of an emulsion without compromising the separation of phases would have been within the scope of a skilled artisan.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 7-16-08 has been considered by the examiner, for the JP reference 2000-256132 for lack of English language translation.

Response to Arguments

Applicant's arguments and also the declaration of Atsushi Tomokuni filed 5-12-09 have been fully considered but they are moot because instant rejection now includes a new combination of references. However, examiner will address the remarks provided by applicants with respect to Watanabe and EP references of record. Applicants argue that in spite of the description of an isotropic surfactant continuous phase, the reference fails to disclose 1-45 wt. % of a lipophilic amphiphile of a fatty alcohol, a fatty acid or a monoalkylphosphoric acid as a component of an isotropic liquid phase exhibiting a bicontinuous phase. It is argued that the basic deficiencies of the primary reference are not cured by EP '910 because EP '910 had been cited for a disclosure of emollients and skin conditioning agents such as fatty acids and fatty alcohols which have been identified by applicants as suitable lipophilic amphiphiles. It is argued that the office action reasons that such a disclosure provides motivation to include fatty acids and/or fatty alcohols in a cosmetic composition for the purposes of treating dry skin and providing a barrier protection.

Applicants' arguments are not persuasive because the new rejection includes the teachings of Lorant, who suggests fatty alcohols as both co-emulsifiers and also as oils essential in the preparation of microemulsions. Thus, the new rejection provides to motivation to employ fatty alcohols of EP not just for their emollient effect but also for their emulsifying property.

Applicants argue that as evidence that addition of a lipophilic amphiphile to a liquid crystal-phase coexisting system according to Watanabe et al. does not provide for

Art Unit: 1611

the claimed composition, applicant encloses a his declaration testing whether there is formation of an isotropic liquid phase exhibiting a bicontinuous structure having a lipophilic amphiphile incorporated therein by adding a lipophilic amphiphile to the liquid crystal composition of Watanabe et al. The declarations provide data on the compositions (labeled B-F) were prepared by adding 1-dodecanol, a lipophilic amphiphile. It is argued that none of Compositions A-E provided any evidence of an isotropic solution having a bicontinuous structure in terms of transparency or light polarization and were illustrative of a liquid crystal-phase coexisting system. It is argued that Composition F, while visibly transparent, was in the form of a w/o type microemulsion and failed to demonstrate light polarization and also failed to dissolve a water-soluble dye. Thus, applicants argue that they provide evidence that an isotropic liquid phase exhibiting a bicontinuous structure does not naturally flow from the suggestion of the cited references. To the contrary, the proposed combination of references provides for a liquid crystal-phase coexisting system. Since an isotropic liquid phase exhibiting a bicontinuous structure does not naturally flow from the cited combination of references, it is argued that the claimed invention having an isotropic liquid phase exhibiting a bicontinuous structure would not have been obvious and accordingly, withdrawal of the rejection under 35 U.S.C. 103(a) is respectfully requested.

Applicants' arguments and the declaration are not persuasive because firstly, applicants have not provided a comparison of the composition of Watanabe modified with an amphiphile and the instant composition. The composition of Watanabe modified

Art Unit: 1611

with an amphiphile that includes all of the claimed components and more particularly in amounts that overlap with the instant. Applicants have not provided any reasoning or rationale as to why instant composition made of the same components such as that suggested by prior art would not result in the claimed an isotropic liquid phase with a bicontinuous structure. In this regard, applicants have not argued that the components such as oil, water, surfactants etc., of Watanabe do not read on the claimed components. Similarly, applicants agree that dodecanol meets the claimed amphiphilic surfactants. If applicants' assertion that instant claimed components result in an isotropic liquid phase with a bicontinuous structure, then the composition resulting from the prior art (tested by applicants) should essentially provide the same structure. Secondly, the results are not commensurate with the scope of the instant claims because while instant claims require the claimed components in 1% to 45% of the surfactants (components B and C) and 3% to 80% of components A, D and E; the compositions tested represent one single concentration within the wide range of concentrations. Applicants have not provided evidence that an isotropic liquid phase with a bicontinuous structure is obtained with any concentration within the claimed range of concentrations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM - 5.30 PM.

Art Unit: 1611

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
August 1, 2009